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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,452	12/28/2001	Howard Milne Chandler	13521-002001	4341

7590

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EXAMINER

CROSS, LATOYA I

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,452

Applicant(s)

CHANDLER ET AL.

Examiner

LaToya L. Cross

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-9 and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,824,268 to Bernstein et al.

Bernstein et al teach a test strip, a device incorporating the test strip and a method for using the test strip within the device for detecting an analyte in a solution of bodily fluid. With respect to claims 1 and 2, Bernstein et al teach a base (housing) having a recess for holding a sample collection/transferring means and a test strip for detecting analytes in a sample. See figure 3. The recess serves to hold a test strip (31) in place, as well as hold the sample collection/transferring means in place. The recess also has two reservoirs (32, 33) for holding a solvent solution (col. 10, lines 58-63), as recited in claim 15. The sample collection/transferring means has a physical end/handle (10) for holding the sample collection/transferring means and an absorbent means (11) for taking up a predetermined amount of sample (col. 10, lines 41-45), as recited in claims 5 and 6. The sample collection/transferring means may be a swab, as recited in claim 4. The test strip may be an immunochromatographic test strip with antibodies and/or analyte binding reagents incorporated therein, as recited in claim 9. With respect to claim 3, Bernstein et al teach that the sample collection means is constructed so that it locks into place in the holding making

Art Unit: 1743

contact with the test strip (col. 10, lines 54-57). With respect to claim 7, Bernstein et al teach a window (37) and an opening (34), shown in figure 3. With respect to method claims 16 and 17, Bernstein et al teach that a sample is collected with the sample collection means. The sample collection means is brought into contact with test strip (present in the device) via the orifice. The solvent present in the solvent reservoir is allowed to contact the sample and carries the sample to the reaction zone, where if the target analyte is present, a visual line will form in the reaction zone. See col. 11, lines 11-39.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(e) in view of the teachings of Bernstein et al.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein et al in view of US Patent 6,027,943 to Kang et al.

Art Unit: 1743

The disclosure of Bernstein et al is described in detail above. Bernstein et al differ from the instantly claimed invention in that there is no disclosure of two or more test insertable testing elements.

Kang et al teach an immunochemical assay device comprising a base member and an array over the base member having a reservoir, wicking membrane and filter zone. In figure 5 and at col. 5, lines 1-15, Kang et al teach an insertable testing elements, each having a wicking material, filter and reagents. Kang et al further teach that the reagent may be the same or different, which permits parallel tests for the same analyte or allows a plurality of different tests on the same sample.

It would have been obvious to one of ordinary skill in the art to incorporate multiple test strips into the device of Bernstein et al. By using several test strips having the same reagents, a more conclusive result will be obtained since the sample will be tested for the same analyte multiple times and the user will not have to rely on one test. By using several test strips having different reagents, more efficient testing of the sample results because multiple test can be run simultaneously with one sample.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Bernstein et al and Kang et al.

6. Claims 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein et al and Kang et al as applied to claims 10-13 above, and further in view of US Patent 6,165,416 to Chandler.

With respect to claims 8 and 14, neither Bernstein et al nor Kang et al teaches a guaiac

Art Unit: 1743

test strip.

Chandler teaches that both immunochromatographic test strips and guaiac test strips are suitable for detecting analytes in bodily samples, especially the detection of occult blood. At col. 11, lines 3-13, the reference teaches that guaiac test strips are the most widespread technology for occult blood testing and the tests are rapid, inexpensive and easy to use.

It would have been obvious to one of ordinary skill in the art to use guaiac test strip in place of the immunochromatographic test strips of Bernstein et al because of their ability to detect analytes simply and fast.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Bernstein et al, Kang et al and Chandler.

Citation of Relevant Prior Art

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- WO publication 98/00712 teaches a chromatographic assay for detecting analytes in a test sample comprising a base member having a receptacle (recess) for inserting a swab containing sample and a recess for inserting a test strip. The swab containing sample is inserted into the device and contacts the test strip, which provides a visual result.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360.

The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..


Art Unit: 1743

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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June 24, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700